

# U.S. National Breast Implant Registry (NBIR) and Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology (PROFILE) Status Update

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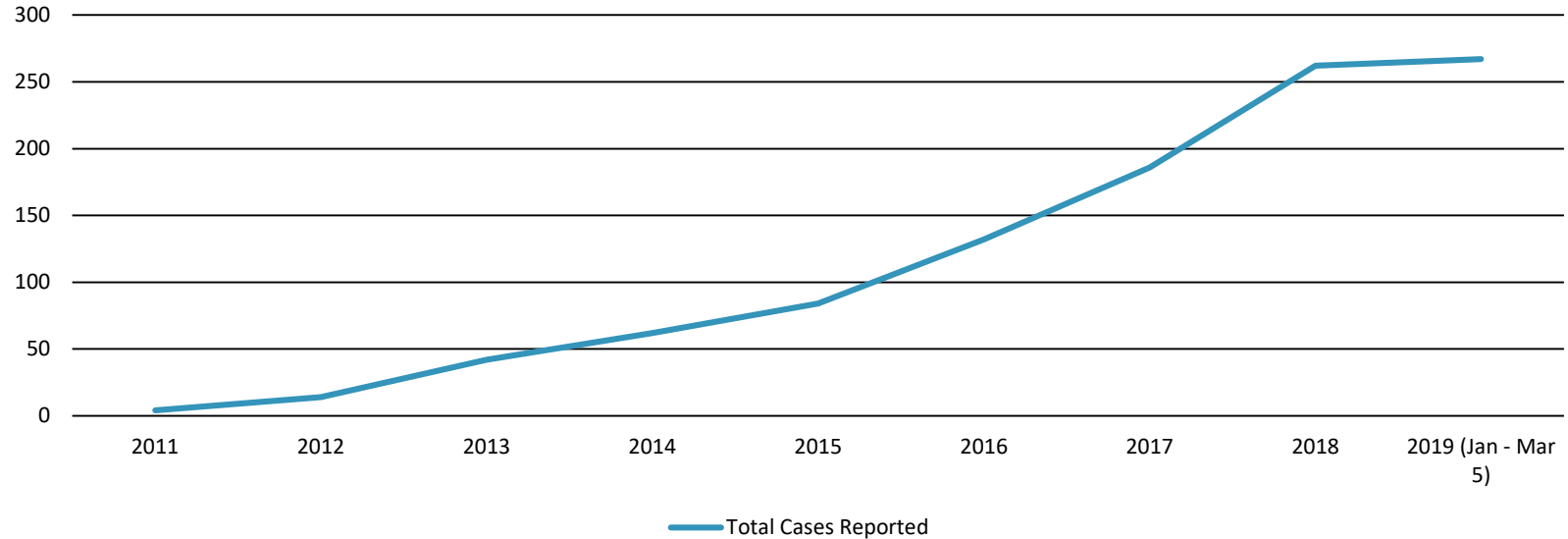
# PROFILE



INVESTIGATING **ALCL**  
& **BREAST IMPLANTS**

# PROFILE Case Information

267 US Cases Reported to PROFILE



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# Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE): Initial Report of Findings, 2012–2018

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**Background:** In January of 2011, the US Food and Drug Administration released a safety communication regarding the potential association between breast implants and anaplastic large cell lymphoma (ALCL). In August of 2012, the American Society of Plastic Surgeons, The Plastic Surgery Foundation, and the Food and Drug Administration signed a cooperative research and development agreement to develop a patient registry entitled the “Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology” (PROFILE).

**Methods:** The first report of the registry findings is presented here.

**Results:** From August of 2012 to March of 2018, a total of 186 distinct cases of breast implant–associated ALCL (BIA-ALCL) in the United States were reported to PROFILE. At the time of this present analysis, complete detailed case report forms have been received for 89 (48%) cases. Median time from implantation of any device to BIA-ALCL diagnosis was 11.0 years (range = 2–44 years;  $n = 89$ ). At the time of presentation, 96% of cases had local symptoms and 9% had concurrent systemic symptoms. The most common local symptom was a periprosthetic fluid collection seen in 86% of patients. All patients had a history of a textured device; there were no patients who had a smooth-only device history. At the time of initial case report submission, 3 deaths were reported.

**Conclusions:** The PROFILE Registry has shown to be an essential tool in unifying the collection of data pertaining to BIA-ALCL. These data have broadened our understanding of the disease and emphasize the critical importance of detailed tracking of BIA-ALCL cases. (*Plast. Reconstr. Surg.* 143: 65S, 2019.)



**NATIONAL BREAST IMPLANT REGISTRY**



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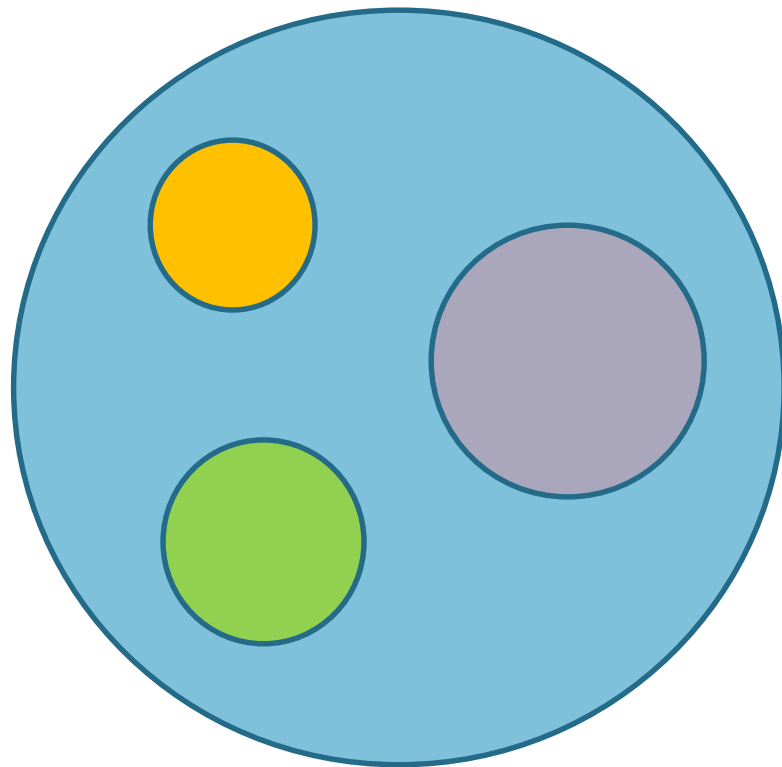


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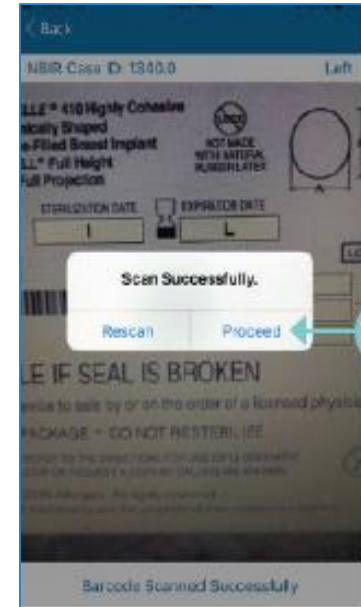


# National Breast Implant Registry: Studies within a cohort



# NBIR Mobile Barcode Scanning App

NBIR app scans and decodes breast implant device barcodes and pushes data contained within the barcode to the NBIR directly from FDA's GUDID database

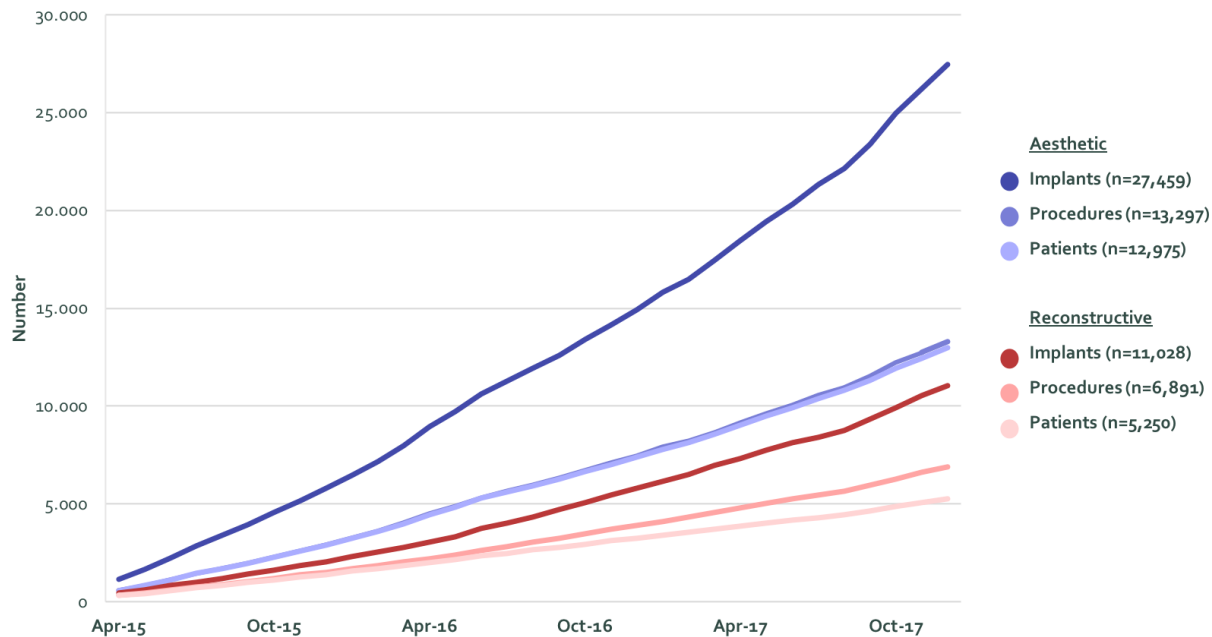


# Next Steps: Device Tracking

- NBIR will be infrastructure for plastic surgeons to complete mandatory implant device tracking
- Anticipated go-live date: July 1, 2019

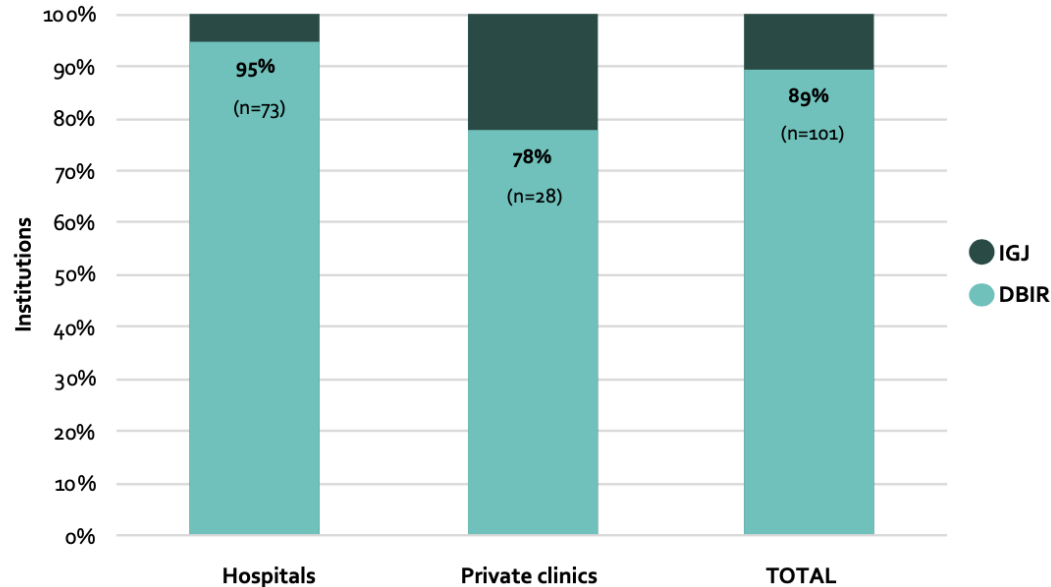


# Dutch National Breast Implant Registry growth over time



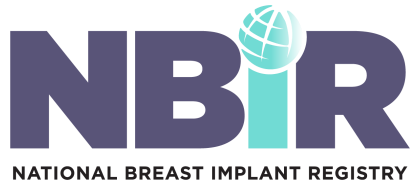
**Current totals**  
**26,000+ patients**  
**54,000+ devices**

# National Coverage of Dutch Registry in 2016

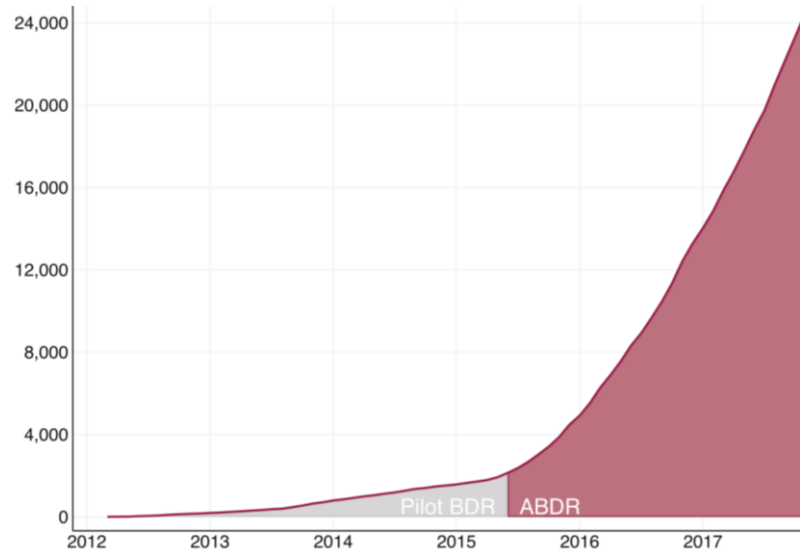


\* IGJ: Dutch Health and Youth Care Inspectorate.

# Next Steps: Patient-Reported Outcomes



# Australian National Breast Implant Registry



As of December 2017,  
25,386 patients



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# Australian National Breast Implant Registry

- 5 questions
- 76 percent response rate in pilot study
- 5,245 cosmetic augmentation, 977 reconstruction patients

ACCEPTED MANUSCRIPT

## **Patient-Reported Outcome Measures for Breast Implant Surgery: A Pilot Study**

Sze Ng, MBBS, Andrea Pusic, MD, Emily Parker, BSc, PhD,  
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*Aesthetic Surgery Journal*, sjz023, <https://doi.org/10.1093/asj/sjz023>

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# Next Steps: Patient-Reported Symptoms and Outcomes



## Key Points

- The ASPS/PSF considers patient safety to be paramount
- Registries are central to ensuring patient safety
- Assessment of patient-reported symptoms and outcomes can be an even more sensitive indicator of safety signals than reoperation



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# Key Points

- The NBIR can and will advance our understanding of breast implant illness and provide safety signal data should new concerns arise about current and future devices
- Participation in the NBIR should be considered a key component of high quality care



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# Thank you



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